

CHAPTER NO. 350

HOUSE BILL NO. 1650

By Representatives McMillan, Shepard, Mike Turner, Hackworth, Gresham, Crider, DuBois, Miller and Mr. Speaker Naifeh and Representatives McDonald, Patton, Ulysses Jones, Litz, Odom, Sherry Jones, Langster, Maddox, Hood, John DeBerry, Black, Brown, Rinks, Garrett, Henri Brooks, Tindell, Davidson, Brenda Turner, Pruitt, Hargrove, Vaughn, Walker, Winningham, West, Fowlkes, Pinion, Cooper, Towns, Sontany, Curtiss, Coleman, Head, Yokley, Briley, Fraley, Ferguson, Larry Turner, Cobb, Harmon, Bone, Fitzhugh, Eldridge, Shaw, Overbey, Brenda Turner, McKee, Newton, Lynn, Phillip Johnson, Dunn, Brooks, Baird, Pleasant, Buttry, Sharp, Sargent, Tidwell, Godsey, Davis, Mumpower, Cochran, Harwell, Kent, Todd, Hensley

Substituted for: Senate Bill No. 1371

By Senators Crutchfield, McLeary, Harper, Kilby, Dixon, Atchley, Beavers, Bryson, Burchett, Burks, Clabough, Cohen, Cooper, Crowe, Ford, Fowler, Graves, Haynes, Henry, Herron, Jackson, Ketron, Kurita, Kyle, McNally, Miller, Norris, Person, Ramsey, Southerland, Trail, Williams and Mr. Speaker Wilder

AN ACT to amend Tennessee Code Annotated, Title 4; Title 8; Title 12; Title 41; Title 53; Title 56; Title 63; Title 68 and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 71, Chapter 5, is amended by adding the following as a new part:

Section 71-5-2401.

(a) There is established in the department of finance and administration a state TennCare pharmacy advisory committee. The committee shall make recommendations regarding a preferred drug list (PDL) to govern all state expenditures for prescription drugs for the TennCare program.

(b) The state TennCare pharmacy advisory committee shall be composed of fifteen (15) members. Except for initial appointments, members shall be appointed to three-year terms. Members shall be appointed as follows:

(1) The governor shall appoint:

(A) One (1) practicing psychiatrist who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Psychiatric Association. The initial appointee shall serve a three-year term;

(B) One (1) practicing nurse practitioner or physician's assistant who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Nurses Association or the Tennessee

Academy of Physician Assistants The initial appointee shall serve a one-year term;

(C) One (1) practicing physician who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Geriatric Society, after consultation with the Tennessee Chapter of the American Association of Retired Persons, who is a gerontologist or whose practice otherwise is primarily among the aged. The initial appointee shall serve a two-year term;

(D) One (1) practicing pediatrician who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee chapter of the American Academy of Pediatrics. The initial appointee shall serve a one-year term;

(E) One (1) family practitioner who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Academy of Family Physicians. The initial appointee shall serve a two-year term;

(F) One (1) practicing cardiologist who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee chapter of the American College of Cardiology. The initial appointee shall serve a three-year term;

(G) One (1) practicing pharmacist who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Chain Drug Council. The initial appointee shall serve a one-year term;

(H) One (1) pharmacy director from a managed care organization participating in the TennCare program. The initial appointee shall serve a two-year term;

(I) One (1) member of an organization engaged in advocacy on behalf of members of the TennCare program. The initial appointee shall serve a three-year term.

(2) The speaker of the senate shall appoint:

(A) One (1) general internist who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Medical Association. The initial appointee shall serve a three-year term.

(B) One (1) practicing pharmacist who is engaged in the retail distribution of prescription drugs who participates in the TennCare program from a list of

three (3) candidates submitted by the Tennessee Pharmacists Association. The initial appointee shall serve a two-year term.

(3) The speaker of the house of representatives shall appoint:

(A) One (1) general internist who participates in the TennCare program from a list of three (3) candidates submitted by the Volunteer State Medical Association. The initial appointee shall serve a one-year term.

(B) One (1) practicing pharmacist who is engaged in the distribution of prescription drugs in the nursing home industry who participates in the TennCare program from a list of three (3) candidates submitted by the Tennessee Pharmacists Association. The initial appointee shall serve a three-year term

(4) The pharmacy director and medical director of TennCare shall serve as ex officio members of the state TennCare pharmacy advisory committee.

(c) In making appointments to the committee, the appointing authorities shall strive to ensure the committee's membership is representative of the state's geographic and demographic composition, with appropriate attention to the representation of women and minorities.

(d) The governor shall appoint a chair and a vice chair of the committee.

(e)

(1) Not less frequently than quarterly, the chair of the committee shall call meetings of the committee and shall preside at all regular and special meetings of the committee, appoint members to any subcommittees established by the committee, prepare agendas with the assistance of staff from the University of Tennessee Health Science Center and the state pharmacy benefit manager, and notify members of their removal from the committee.

(2) The vice chair shall exercise all powers of the chair in the event of the absence or inability of the chair to serve and shall perform other duties as the chair may assign to the vice chair.

(f) Committee meetings shall follow Robert's Revised Rules of Order.

(g) Committee meetings shall be subject to the provisions of title 8, chapter 44, provided however, that notice of meetings and the agenda therefor shall be made available to the public not less than ten days prior to any meeting of the committee.

(h) Committee decisions shall be made based on affirmative votes of the majority of members present at official meetings.

(i) The committee shall keep minutes of all meetings including votes on all recommendations regarding drugs to be included on the state preferred drug list.

(j) A quorum shall be established by the presence of eight (8) committee members present at an official meeting.

(k) The chair may request that other physicians, pharmacists, faculty members of institutions of higher learning, or medical experts who participate in various sub-specialties act as consultants to the committee as needed.

(l) Vacancies shall be filled by the appropriate appointing authority in the same manner as full terms for the remainder of the unexpired term.

Section 71-5-2402. A state TennCare pharmacy advisory committee member shall be removed by the commissioner of finance and administration from the committee for any of the following causes:

(1) Absence from two (2) consecutive meetings without contacting the chair or the vice chair with a satisfactory explanation;

(2) Absence from three (3) meetings in a single year without contacting the chair or the vice chair with a satisfactory explanation;

(3) Violation of the provisions of section 71-5-2403(a) and (b).

(4) Violation of the provisions of Section 71-5-194(d)

Section 71-5-2403.

(a) Members of the state TennCare pharmacy advisory committee shall not enter any financial relationships with pharmaceutical manufacturers or their affiliates during their tenure on the state TennCare pharmacy advisory committee. A member shall not entertain individual lobbying or marketing, or participate in any other activity or discussions with pharmaceutical manufacturers or their representatives for the purpose of influencing the PDL that would call into question the member's impartiality in determining drugs to recommend for inclusion on a state preferred drug list. Nothing herein shall prohibit a member from engaging in common business practices or prohibit communications to or from the member that occur in the ordinary course of the member's business or professional activities.

(b) A conflict of interest exists when the member has a significant personal, professional or monetary interest in a matter under consideration by the state TennCare pharmacy advisory committee. Persons being considered for membership on the state TennCare pharmacy advisory committee shall disclose if they have a real or apparent conflict of interest. Conflicts of interest may include, but shall not be limited to, being the recipient of a grant, hired as a consultant, being part of a speakers bureau, a major stock holder, or the recipient of

other financial support from an organization likely to benefit financially from the outcome of the state TennCare pharmacy advisory committee's work.

(c) Members shall dispose of matters before the committee in an unbiased and professional manner. In the event that a matter being considered by the committee presents a real or apparent conflict of interest, such members shall disclose the same to the chair and recuse themselves from any official action on the matter.

(d) Members shall receive no compensation for their service on the state TennCare pharmacy advisory committee but may be reimbursed for those expenses allowed by the provisions of the comprehensive travel regulations promulgated by the department of finance and administration and approved by the attorney general and reporter.

Section 71-5-2404.

(a) The state TennCare pharmacy advisory committee shall submit to the TennCare bureau both specific and general recommendations for drugs to be included on any state preferred drug list (PDL) adopted by the bureau. The committee shall also submit recommendations to the bureau regarding computerized, voice, and written prior authorization, including prior authorization criteria, and step therapy.

(b) The state TennCare pharmacy advisory committee shall include evidence-based research in making its recommendations for drugs to be included on the PDL.

(c) The University of Tennessee College of Pharmacy shall provide the state TennCare pharmacy advisory committee with clinical and economic research and utilization information as requested on drugs and drug classes.

(d) The TennCare bureau shall consider the recommendations of the state TennCare pharmacy advisory committee in amending or revising any PDL adopted by the bureau to apply to pharmacy expenditures within the TennCare program. The recommendations of the committee are advisory only, and the bureau may adopt or amend a PDL regardless of whether it has received any recommendations from the committee. It is the legislative intent that, insofar as practical, the TennCare bureau shall have the benefit of the committee's recommendations prior to implementing a PDL or portions thereof.

SECTION 2. Tennessee Code Annotated, Title 4, Chapter 3, Part 10, is amended by adding the following as new section to be appropriately designated:

Section 4-3-1013.

(a) The TennCare bureau is authorized to develop prescription drug programs and to contract with one or more pharmacy benefit managers (PBMs) or other appropriate third party contractors to administer all or a portion of such prescription drug programs for the TennCare program. It is the legislative intent that, insofar as practical,

any such pharmacy programs shall be developed and implemented in a manner that seeks to minimize undue disruption in successful drug therapies for current TennCare enrollees.

(b) Under such a contract, a PBM may be directed by the TennCare bureau to:

(1) Provide information to the state TennCare pharmacy advisory committee to making recommendations related to a state preferred drug list (PDL);

(2) Provide claims processing and administrative services for the TennCare program;

(3) Provide data on utilization patterns to the bureau of TennCare, the department of finance and administration, TennCare managed care organizations, the University of Tennessee Health Science Center, and other entities determined by the TennCare bureau;

(4) Conduct prospective and retrospective drug utilization review as directed by the bureau of TennCare;

(5) Establish procedures for determining potential liability of third party payers, including but not limited to Medicare and private insurance companies, for persons receiving pharmacy services through the state of Tennessee;

(6) Maintain a retail pharmacy network to provide prescription drugs through state programs;

(7) Set pharmacy reimbursement rates and dispensing fee schedules necessary to maintain an adequate retail pharmacy network and increase the cost-effectiveness of state pharmacy purchases;

(8) Negotiate supplemental rebates with pharmaceutical manufacturers for prescription drug expenditures;

(9) Propose other initiatives to the bureau of TennCare to maintain or improve patient care while reducing prescription drug costs; and

(10) Provide other services as directed by the bureau of TennCare.

(c) The state TennCare program shall be authorized to receive one hundred percent (100%) of all rebates and any other financial incentives directly or indirectly resulting from the state's contract with any PBM.

(d) The PBM contract may include performance goals and financial incentives for success or failure in attaining those goals. It is the legislative intent that such goals and incentives shall include the reliable and timely performance of any system of prior authorization that may be implemented pursuant to pharmacy programs authorized hereby.

SECTION 3. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

Section 71-5-194.

(a) The bureau of TennCare is authorized to remove pharmacy services from managed care organization (MCO) contracts and assume direct responsibility for all TennCare pharmacy purchases.

(b) The bureau of TennCare is authorized to implement tiered copayments and prior authorization and step therapy requirements based on the state preferred drug list (PDL), provided, however, any prior approval process shall, as a minimum, comply with the provisions of 42 USC 1396(r)-8(d)(5), the provisions of which require a response to a request for prior authorization within 24 hours and further require at least a 72-hour supply of a covered outpatient drug in an emergency situation.

(c) The bureau of TennCare, through a state pharmacy benefit manager (PBM) or on its own, is authorized to negotiate supplemental manufacturer rebates for TennCare prescription drug purchases, provided that when conducting such negotiations, the bureau and/or PBM shall utilize the Average Manufacturer's Price (AMP), as defined in 42 USC 1396r-8(k)(1), as the cost basis for the product.

(d) Notwithstanding any other law to the contrary, all information and documents containing trade secrets, proprietary information, rebate amounts for individual drugs or individual manufacturers, percent of rebate for individual drugs or individual manufacturers, and manufacturer's pricing which are contained in records of the TennCare bureau, the State of Tennessee and its agents shall be confidential and shall not be a public record for the purposes of title 10, chapter 7, part 5. Nothing in this subsection shall be construed to prohibit the TennCare bureau and the State of Tennessee from disclosing the information covered by this subsection to members of the state TennCare pharmacy advisory committee, who shall be deemed agents of the State of Tennessee for purposes of this subsection.

(e) Notwithstanding any other law to the contrary, those portions of meetings of the state TennCare pharmacy advisory committee at which information described in subsection (d) is disclosed for discussion are exempt from the provisions of title 8, chapter 44.

SECTION 4. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

Section 71-5-195.

(a) If necessary, the bureau of TennCare is authorized to seek a research and demonstration waiver under section 1115 of the federal Social Security Act from the U.S. department of health and human services to create a TennCare Rx program, subject to funding by the general assembly and the terms and conditions imposed by the waiver.

(b) To the extent and only to the extent permitted by federal law or the terms of the waiver, the TennCare Rx program may provide a prescription benefit to individuals lacking prescription drug insurance coverage who meet criteria established by the bureau of TennCare and the general assembly in its annual appropriation bill.

(c) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare may implement tiered co-payments and prior authorization and step therapy requirements for the TennCare Rx program based on the state preferred drug list (PDL).

(d) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare, through a state pharmacy benefit manager (PBM) or on its own, may negotiate manufacturer rebates for TennCare Rx prescription drug purchases.

(e) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare may establish an open enrollment period based on appropriations from the general assembly.

(f) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare may contract with another department or a private entity to conduct eligibility determination. The bureau or a contracted entity may implement an eligibility determination process to ensure participants comply with eligibility standards set by the bureau and the general assembly.

(g) As permitted by the waiver or federal law, program participants may purchase prescription drugs through pharmacies participating in the state network.

(h) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare may establish an enrollment fee to defray administrative expenses associated with the program.

SECTION 5. Tennessee Code Annotated, Title 4, Chapter 3, Part 10, is amended by adding the following as a new section:

Section 4-3-1014

In accordance with applicable provisions of law:

(a) The department of finance and administration is authorized to create a program whereby local government entities, including but not limited to county jails, can purchase prescription drugs through state methods at reduced prices.

(b) The department of general services is authorized to sell drugs to participating local entities that have certified pharmacists on staff or require wholesalers contracting with the department of general services to sell prescription drugs to participating local entities at discounted rates.

SECTION 6. If a court of competent jurisdiction enjoins, restrains or stays programs authorized by this act, then the department of finance and administration or the

bureau of TennCare as appropriate is authorized to proceed to implement as appropriate those portions of this act that have not been lawfully enjoined, restrained or stayed.

SECTION 7. Tennessee Code Annotated, Section 4-29-226(a), is amended by adding the following new items to be appropriately designated:

(___) State TennCare pharmacy advisory committee.

SECTION 8. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 9. This act shall take effect on becoming a law, the public welfare requiring it.

PASSED: May 27, 2003


JIMMY RAIFEH, SPEAKER
HOUSE OF REPRESENTATIVES


JOHN S. WILDER
SPEAKER OF THE SENATE

APPROVED this 13th day of June 2003


PHIL BREDESEN, GOVERNOR